UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,433	02/27/2004	Mark Thomas Muldoon	19596-0571 (45738-296417)	5696

23370 7590 05/19/2009

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
SUITE 2800
ATLANTA, GA 30309

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,433	MULDOON ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13,15-17 and 20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2009 has been entered.

Amendment Entry

2. The amendment filed March 2, 2008 has been entered. Claims 10, 12, 15, 16 and 20 have been amended. Claims 1-9, 14 and 18-19 are cancelled.

Election/Restrictions

3. Applicant's assert that while claim 20 does not recite SEQ ID NO:2, it should be examined because the sequences are similar and are directed to troponin. However, claim 20 is independent or distinct because SEQ ID NO: 3-6, 9-13 and 15-35 do not share physical and functional characteristics with elected SEQ ID NO:2. The amino acid sequences constitute patentably distinct inventions which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each sequence comprises separate and distinct amino acid sequences that do not share a

substantial structural feature disclosed as being essential to the utility of the invention. The number of amino acids or similarity of the sequences is not the defining criteria for determining whether the sequences of claim 20 should also be considered.

If applicants desire all of the sequences to be considered, then applicant should submit evidence showing that the sequences are obvious variants of each other or clearly admit on the record that the sequences are obvious variants of each other. Since, applicant has not made any showings, applicants' argument is not persuasive, thus requirement is still deemed proper. Thus, claim 20 is withdrawn from consideration.

4. Claims 10-13 and 15-17 and SEQ ID NO:2 are under consideration in this office action.

Withdrawal of Rejections

5. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The new matter rejection of claims 10-13 and 15-17 under 35 U.S.C. 112, first paragraph; and

b) The rejection of claims 10-13 and 15-17 under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 10-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001) in view of Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

The rejection is on the grounds that it would have been *prima facie* obvious at the time of applicants' invention to apply the ligand reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2 of Sheng et al, to the assay for detecting a mammalian troponin molecule in a sample as taught by Chen et al., in order to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of species adulteration.

Response to Arguments

7. Applicant's arguments filed March 2, 2009 have been fully considered but they are not persuasive.

Applicants assert that the monoclonal antibody of Chen et al., do not detect a troponin molecule from at least two mammalian species where a peptide having SEQ ID NO:2 was used to immunize an animal and produce an antibody. In response to

applicant's arguments against the Chen et al., reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the claims require a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO:2; Sheng et al., disclose SEQ ID NO:2. The claims require a ligand that is an antibody produced by immunizing an animal with a peptide having SEQ ID NO:2. Chen et al., teach the production of antibodies by immunizing mice with skeletal muscle troponin I. Sheng et al., already teach SEQ ID NO:2 which is a skeletal muscle troponin I molecule. No more than routine skill would have been required to exchange the antibody ligand of Chen et al., for the available peptide of Sheng et al., since Chen et al., teach the desire to have a variety of mammalian troponin ligands along with immunization of peptides to procedure antibodies when all the claimed elements were known in the prior art and one skilled in the art could have combined and exchanged the peptides and ligands as claimed by known methods with no change in their respective functions and the combination would have been yielded predictable to one of ordinary skill in the art at the time of the invention.

Applicants argue that the MT1 antibody is capable of differentiating between mammalian and avian species. In response to applicant's argument that the references fail to show the MT1 antibody of applicant's invention, it is noted that the features upon which applicant relies i.e., the MT1 antibody are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to Applicants argument that the instant ligand is specific for a mammalian troponin molecule from at least two species; it is the position of the Office that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *re re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364,1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). In this case, Sheng et al., disclose a peptide having SEQ ID NO:2. Therefore the peptide having SEQ ID NO:2 has the same abilities as the instantly claimed peptide having SEQ ID NO: 2; like immunizing an animal with identical peptides to produce an antibody specific for a molecule from at least two species and not specific to an avian molecule.

Applicants' assert that Chen et al., in view of Sheng et al., need to recite that the identical amino acid sequences have the ability to detect troponin molecules from at

least two mammalian species and not detect the avian molecules. However the rejection is maintained because the prior art peptide is identical to the instantly claimed peptide. The prior art references teach how to produce the ligand, i.e., by immunization of an animal to produce antibodies. Therefore the fact that the prior art is silent as the inherent characteristics of the produced ligand claimed in terms of a function, property or characteristic not explicitly disclosed by the reference, is not persuasive because one of ordinary skill in the art would have a reasonable expectation of success by exchanging the troponin peptides of Chen et al., for the troponin peptide of Sheng et al., which has SEQ ID NO:2 because Chen et al., teach the desire to have specific mammalian troponin species markers which do not detect avian troponin for detection immunoassays. Furthermore, Sheng et al., even finds higher levels of homology between rabbit and mouse nucleotide and amino acids sequences. Therefore applicants' argument is not persuasive.

Applicants argue that the Office has not provided an apparent reason to combine the teachings of Chen and Sheng et al. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Office has set forth multiple rationales to support the conclusion of obviousness. For instance, a reasonable expectation of success has been shown. In this case, the rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in

the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727(2007).

Furthermore, the Office set forth that some degree of predictability is shown. In this case, the claims would have been obvious because the substitution of a similar or equivalent yet alternative mammalian skeletal muscle troponin I for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Additionally, modifying the antibody production using the troponin I peptide of Chen et al., for a peptide having SEQ ID NO:2 was recognized as part of the ordinary capabilities of one skilled in the art while advantageously improving species identification immunoassays; especially when Chen et al., specifically states the desire to have species marker antigens (peptides) that would substantially increase the chance of eliciting specific antibodies. Thus predictability and a reasonable expectation of success was clearly set forth, therefore applicants arguments are not persuasive.

Applicants' urge that the teachings of Chen et al., provide no reasonable expectation of success or motivation to use the amino acid sequence of troponin I from any other species to generate antibodies that recognize troponin I from more than one species. In this case, it would have been prima facie obvious to combine the invention of Chen et al., and Sheng et al., to advantageously detect mammalian troponin in adulterated meat samples since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Furthermore, Chen et al., state that the selected markers are indispensable in developing immunoassays for the detection of species origins in animal feed.

Thus, applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645